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St. Jude Medical Neuromodulation Division 6901 Preston Road Plano TX 75024 OFFICE OF PETITIONS

In re Application of

Sheffield et al. : ON APPLICATION FOR PATENT

Application No.: 10/731892 : TERM ADJUSTMENT Filing or 371(c) Date: 12/09/2003 : RECONSIDERATION

Patent Number: 7,565,199

Issue Date: 07/21/2009
Attorney Docket Number: 337348055US1 (09-115 US)

This is a Decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT RECONSIDERATION UNDER 37 C.F.R. § 1.705(D)," filed September 21, 2009. Patentees submit that the correct patent term adjustment to be indicated on the patent is 579 days, not 146 days.

The request for reconsideration patent term adjustment is **DISMISSED**.

On July 21, 2009, the above-identified application matured into U.S. Patent No. 7,565,199 with a patent term adjustment of 146 days. This application for patent term adjustment was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentees assert that the Office failed to properly account for the delay under 35 U.S.C.§ 154(b)(1)(A), the "A delay," which patentees assert is 458 days, and that the Office failed to properly account for the delay under 35 U.S.C. § 154(b)(1)(B), the "B delay," which patentees assert if 485 days, as the first Request for Continued Examination ("RCE") was filed on April 7, 2008. Patentees further assert that the "A delay" and the "B delay" do not overlap. Accordingly, Patentees assert that the correct patent term adjustment for this patent is 579 days (458 days of "A Delay" plus 485 days of "B Delay" less zero overlapping days less by 364 days of Applicant delay).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

The Office asserts that as of the filing of the RCE on April 7, 2008, the application was pending three years and 484 days after its filing date (December 10, 2006 to April 6, 2008). The Office

agrees that at the time of filing of the RCE on April 7, 2008, certain action detailed was not taken within a specified time frame, and thus, the entry of a period of adjustment of 433 days is correct. At issue is whether patentees should accrue 484 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 433 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that the period of 433 days of examination delay under 37 CFR 1.702(a) overlaps with the period of 484 days of delay in issuing the patent. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the

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corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(1)(A) is the entire period during which the application was pending before the Office, December 9, 2003, to April 6, 2008, the day before the date of filing of the RCE on April 7, 2008. Prior to the filing of the RCE, 433 days of patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application. All of the 433 days of examination delay overlap with the 484 days for Office delay in issuing the patent. During that time, the issuance of the patent

¹ The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

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was delayed by 484 days, not 484 days + 433 days. The Office took 14 months and 433 days to issue a first Office action. Nonetheless, given the initial 433 days of Office examination delay and the time allowed within the time frames for processing and examination, at the time of filing of the RCE, the application was pending three years and 484 days after its filing date. However, the Office did not delay 484 days and also delay an additional 433 days.

Accordingly, at issuance, the Office entered an overall adjustment of 146 days, having considered the Office delay under the three-year pendency provision in conjunction with the examination delay under 37 CFR 1.702(a) and the applicant delay under 37 CFR 1.704.

In view thereof, no additional patent term adjustment has been accorded.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The address given on the petition differs from the address of record. A change of address should be filed in this case in accordance with MPEP 601.03. A courtesy copy of this decision is being mailed to the address noted on the petition. However, until otherwise instructed, all future correspondence regarding this application will be mailed solely to the address of record. Applicant is further advised that, in patented files: requests for changes of correspondence address, powers of attorney, revocations of powers of attorney, withdrawal of attorney and submissions under 37 CFR 1.501: Designation of, or changes to, a fee address, should be addressed to Mail Stop M Correspondence.

Telephone inquiries specific to this matter should be directed to Attorney Derek Woods, at (571) 272-3232.

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